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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/889,825	07/08/97	LEV A	6530.0060

QM41/0929
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EXAMINER	
PEFFLEY, M	
ART UNIT	PAPER NUMBER
3736	6

DATE MAILED: 09/29/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.	Applicant(s)
08/889,825	Lev
Examiner	**Group Art Unit**
Michael Peffley	3736

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-79* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-79* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims positively include the human body (e.g. "organ" and "bladder") as part of the invention, the human body being non-statutory subject matter. More specifically, the Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, issued a notice in the Official Gazette stating, "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 USC 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution". 1077 OG 24(1987), reprinted in 1146 TMOG 24(1993).

In order to overcome this rejection, applicant's claims must be amended to recite language such as "adapted to contact the bladder" or similar recitation. Claims 1-11, 14, 16, 33, 40, 41 and 43-45 all include positive recitation of the human body.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-47 are unclear in the scope of the invention, particularly since they include recitation of the human body (see 35 USC 101 rejection, supra).

Claim 1 further lacks proper antecedent basis for "the proximal end" (line 9); "the power supply cables" (line 10); "the ends of said thermocouples" (line 12); and "the outwardly deflected ends" (line 14).

Also, claim 1 fails to provide sufficient structure to support the limitations, and is further unclear whether or not a fluid source is being claimed. The claims inferentially recite a fluid source in the preamble (i.e. "and adapted to receive multiple injected liquid flows"), which recitation is not a positive inclusion of the fluid or fluid source. However, the body of the claims positively recite the fluid (i.e. "said radiating antenna (1) is submerged within a flow"), thereby making it unclear if the fluid is positively to be included as part of the invention. Clarification is necessary.

Claim 2 lacks proper antecedent basis for "the distal end" (line 6) ; "the proximal end" (line 8); "the power supply cables" (line 9); "the ends" (line 10); and "the outwardly deflected

ends" (line 12). Claim 2 is also unclear with respect to the recitation of the fluid, similar to claim 1.

Claim 3 lacks proper antecedent basis for "the distal end" (line 6); "the proximal end" (line 8); "the ends" (line 10); and "the outwardly deflected ends" (line 12). As with claims 1 and 2, claim 3 is unclear with whether the fluid is to positively recited as part of the invention.

Claims 4, 5, 7, 14, 16, 18 and 19 are all unclear with the recitation of fluid, particularly with whether the fluid and a fluid source are positively being claimed. See rejection of claim 1.

Claim 11 fails to provide sufficient structural cooperation for the channel. In particular, it is not clear how the channel is structurally related to the other elements of the invention.

Claim 20 fails to provide sufficient structure (i.e. an energy source) to support the frequency range of the antenna.

Similarly, claim 35 fails to provide sufficient structure to support the limitation of the balloon being filled with a second fluid.

Claims 43-45 fail to set forth structure which further limits the invention. Moreover, these claims recite only non-statutory subject matter (i.e. parts of a body).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-20 and 24-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al ('435) in further view of the teaching of Quint ('044).

Turner et al disclose a radiating device for providing microwave hyperthermia to tissue. The device comprises a catheter (52) with a balloon (76) at the distal end thereof. The catheter includes several lumens (56,59,60) for providing and removing various fluids. In particular, lumen (59) delivers a cooling fluid past the antenna (which is a shielded antenna) to tissue, while lumen (56) returns the fluid from a body cavity. A separate lumen (60) is used for inflating the balloon. The examiner takes official notice that it is generally well known in the art to use any type of inflation medium, including various gases and liquids. Turner et al also disclose various temperature sensing means locate along the length of the catheter for determining tissue temperature (column 11, lines 24-47), but fail to disclose specific temperature sensors which are expandable into contact with tissue. The Turner et al temperature sensor means are retained within notches (i.e. sheath 22) along the catheter length, the sensors also being sealed by the sheath. The use of polytetrafluoroethylene for making catheters and sheaths is very well known in the art.

Quint discloses a similar hyperthermia device whereby heat is applied to a hollow organ via contact of an expandable (i.e. balloon) member with the wall of the organ. Further, Quint disclose the specific use of multiple temperature sensors (46) which are located on the external

surface of the balloon and brought into contact with tissue when the balloon is expanded. To have provided such expandable temperature sensors on the Turner et al balloon would have been an obvious design consideration.

With regard to the use of a cytotoxic substance, the examiner takes official notice that it is generally well known in the art to provide a variety of substances to tissue during treatment with high frequency energy. Use of any well known substance to enhance the effects of a high frequency treatment would be well within the purview of the skilled artisan (see, for example, Abele et al).

Finally, the method of using the Turner et al device, as modified by the teaching of Quint, is inherent to its structure and the Turner et al and Quint disclosures.

To have provided the Turner et al device with temperature sensor which are expandable into contact with tissue for monitoring tissue temperature would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Quint.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al ('435) and Quint ('044) as applied to the claims immediately above, and further in view of the teaching of Sogawa et al ('383).

The combination of Turner et al and Quint has been addressed previously. While Turner et al disclose the use of a microwave antenna for transmitting energy to tissue, there is no specific disclosure of using a linear dipole antenna as set forth in claims 21 and 22.

Sogawa et al disclose a similar microwave hyperthermia device, and further teach that the use of linear dipole antennas for such hyperthermia devices is generally well known (column 1, lines 59-65). Turner et al disclose an antenna structure comprising a coil shaped segment (14) and a linear conductor (16d), and the use of such a microwave in a linear dipole antenna would be an obvious design choice.

To have provided the Turner et al device, as modified by the teaching of Quint, with a linear dipole antenna in lieu of the Turner et al antenna would have been an obvious modification for one of ordinary skill in the art. Motivation for such a combination is found in the Sogawa et al reference which discloses the known use of linear dipole antennas for hyperthermia treatment devices including a catheter, balloon and cooling medium.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abele et al ('312) disclose a high frequency device whereby a number of substances are injected into tissue to enhance thermal effects of the device. Neilson et al ('518) and Rosen et al ('717) disclose a microwave hyperthermia device similar in nature to that disclosed by Turner et al. Lee ('321) discloses an RF hyperthermia device with a balloon and a means to provide a cooling fluid, and Brown et al ('320) disclose a laser balloon hyperthermia device which includes expandable temperature sensors (34,35) located within the balloon. Finally, Durgin, Jr et al

('222) also disclose the use of several substances which may be injected into tissue during high frequency procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Monday through Friday from 7:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer Bahr, can be reached on (703) 308-1066.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp
Primary Examiner
Art Unit 3736
September 15, 1998

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER
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